UNITED STATES DISTRICT COURT FOR THE SOUTHER DISTRICT OF TEXAS MCALLEN DIVISION

ACUTE CARE AMBULANCE SERVICE,	§
L.L.C.,	§
	§
Plaintiff,	§
	§
VS.	§ CIVIL ACTION NO. 7:20-cv-00217
	§
ALEX M. AZAR II,	§
SECRETARY OF THE UNITED STATES	§
DEPARTMENT OF HEALTH	§
AND HUMAN SERVICES,	§
	§
Defendant.	§

<u>DEFENDANT'S REPONSE TO</u> PLAINTIFF'S MOTION FOR A PRELIMINARY INJUNCTION

Respectfully submitted,

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I. NATURE AND STAGE OF PROCEEDING

The Secretary used his statutory and regulatory authority to suspend Medicare payments to Plaintiff after he received credible allegations that Plaintiff was defrauding the Medicare program. *See* 42 U.S.C. § 1395y(o), 42 C.F.R. § 405.371(a)(2). The Secretary received information that Plaintiff repeatedly submitted improper claims and falsified claim documentation. The Secretary is currently investigating these fraud allegations. Plaintiff, as allowed by Medicare regulations, submitted a rebuttal statement asserting that its payment should not be suspending because of the COVID-19 emergency. In response, the Secretary rejected Plaintiff's assertions - stating that the COVID-19 emergency did not justify termination of the suspension when there are potentially fraudulent claims and that there were other ambulance service providers available to Medicare beneficiaries.

Plaintiff filed its Complaint (Doc. 1) asserting that the Secretary's suspension of its Medicare payments - during the COVID-19 emergency - was improper. The Secretary responded to Plaintiff's complaint by filing a motion to dismiss (MTD) under Fed. R. Civ. P. 12(b)(1) and (6). Doc. 14. In his MTD, the Secretary demonstrated that Plaintiff failed to provide a jurisdictional basis for its action and a legal basis for Plaintiff's claims. *Id.*

Plaintiff also requests a preliminary injunction, arguing that it is entitled to mandatory injunctive relief stopping the payment suspension and requiring the payment of claims held in suspense. *See* Doc. 8, 9. Essentially, Plaintiff repeats its complaint assertions – arguing that the Secretary should not have suspended its Medicare payments during the COVID-19 emergency and asserting that it is entitled to a hearing. Doc. 8, 9. However, Plaintiff has not pointed to any statute, regulation or court decision that prohibits the Secretary from suspending a provider's

Medicare payments when he receives a credible allegation of fraud or requires the Secretary to provide a hearing before doing so. Indeed, Medicare statutes and regulations specifically allow the Secretary to suspend Medicare payments when he receives credible allegations of fraud.

Therefore, the Secretary files this response requesting that Plaintiff's motion for a preliminary injunction be denied because Plaintiff cannot show it is entitled to injunctive relief.

II. ISSUE

Considering that Congress has authorized the Secretary to suspend Medicare payments when he receives credible allegations of fraud and the Secretary received credible fraud allegations concerning Plaintiff's Medicare claims, should this Court grant Plaintiff's motion for a preliminary injunction and set aside the Secretary's lawful Medicare payment suspension?

III. STANDARD OF REVIEW

Plaintiff seeks a preliminary injunction to "enjoin a Medicare payment suspension imposed during the COVID-19 pandemic and national emergency, and release all suspended payments, until the national emergency is lifted or Defendant otherwise gives notice and an opportunity for a hearing on the adverse action in conformance with Due Process of Law." Doc. 9, at 7. A preliminary injunction is an "extraordinary and drastic" remedy, and "should only be granted when the movant has clearly carried the burden of persuasion." *Anderson v. Jackson*, 556 F.3d 351, 360 (5th Cir. 2009). A party seeking a preliminary injunction must show: (1) a "substantial likelihood of success on the merits, (2) a substantial threat of irreparable injury if the injunction is not issued, (3) that the threatened injury if the injunction is denied outweighs any harm that will result if the injunction is granted, and (4) that the grant of the injunction will not disserve the public interest." *Bynum v. Landreth*, 566 F.3d 442, 445 (5th Cir. 2009) (*quoting Speaks v. Kruse*, 445 F.3d 396, 399-400 (5th Cir. 2006)).

Injunctions are classified as either prohibitory or mandatory. See Meghrig v. KFC W., *Inc.*, 516 U.S. 479, 484 (1996). A prohibitory injunction restrains a party from further action; whereas a mandatory injunction (such as returning payments held during a payment suspension) orders a party to take certain actions. *Id.* Although mandatory and prohibitory injunctions are governed by the same standard, "mandatory preliminary relief is subject to heightened scrutiny and should not be issued unless the facts and law clearly favor the moving party." Dahl v. HEM Pharms. Corp., 7 F.3d 1399, 1403 (9th Cir. 1993) (internal quotation marks omitted). "When a plaintiff applies for a mandatory preliminary injunction, such relief 'should not be granted except in rare instances in which the facts and law are clearly in favor of the moving party. Exhibitors Poster Exch. Inc. v. National Screen Serv. Corp., 441 F.2d 560, 561 (5th Cir. 1971) (per curiam) (quoting *Miami Beach*, 256 F.2d at 415); *Harris v. Wilters*, 596 F.2d 678, 680 (5th Cir. 1979) ("Only in rare instances is the issuance of a mandatory preliminary injunction proper."); Martinez v. Mathews, 544 F.2d 1233, 1243 (5th Cir. 1976) ("Mandatory preliminary relief, which goes well beyond simply maintaining the status quo pendente lite, is particularly disfavored, and should not be issued unless the facts and law clearly favor the moving party.").

IV. SUMMARY OF ARGUMENT

Plaintiff has failed to meet the requirements for a mandatory preliminary injunction.

First, Plaintiff cannot show a substantial likelihood that it will prevail on the merits because its complaint cannot survive the Secretary's Motion to Dismiss (Doc. 14). Plaintiff's action should be dismissed under Fed. R. Civ. P. 12(b)(1) and (6) because Plaintiff cannot show that this Court has jurisdiction to hear its action or that it has presented claims that are entitled to relief.

Congress requires Plaintiff to channel its claims through the administrative process before seeking relief in this Court but Plaintiff failed to do so. Likewise, Plaintiff has failed to state a

claim for which it is entitled to relief because it failed to plead facts that are sufficient to state a claim for injunctive relief that is plausible on its face. And in regards to its claims on behalf of its patients, Plaintiff cannot show that it has standing to bring due process claims on behalf of its patients or that the Court has jurisdiction over those claims. Therefore, the Court should deny Plaintiff's preliminary injunction and dismiss its Complaint.

But even if the Court were to find that it has jurisdiction to consider Plaintiff's claims, Plaintiff cannot show a clear entitlement to the mandatory injunctive relief that it seeks. First, Plaintiff cannot clearly demonstrate that it has substantial likelihood of success on the merits of its due process claims because Plaintiff cannot clearly show that it meets the due process elements in *Mathews v. Eldridge*, 424 U.S. 319 (1976). Plaintiff cannot show that: (1) it has property interest in potentially fraudulent Medicare reimbursements; (2) its request for a hearing will add significant probable value to the suspension process: or (3) that its interest in having a pre-suspension hearing is greater than the Government's interest in protecting the Medicare Trust fund. Plaintiff also cannot clearly show a likelihood of success on its patient's due process claims because Plaintiff cannot point to any statute, regulation or court decision that gives its patients a right to receive its services while under a fraud payment suspension.

Second, Plaintiff cannot clear show irreparable harm if the mandatory injunctive relief that it seeks is denied. Plaintiff's contention that it will be forced out of business if the suspension continues is entirely unsubstantiated. Plaintiff has received over \$60,000 in funding through the Coronavirus Aid, Relief, and Economic Security Act, Pub. L. No. 116-136 (CARES Act). With regard to Plaintiff's patients, the Secretary has conducted an access to care review and determined that Medicare beneficiaries would not lose access to care if Plaintiff chose to discontinue providing ambulance services.

Third, in contrast to Plaintiff's economic interests and low risk of patient disruption, the Secretary's interest in preserving the integrity of the Medicare program and protect the dwindling Medicare Trust funds is paramount.

Lastly, issuance of the injunction sought by Plaintiff would strongly disserve the public interest. The Secretary, has an interest in ensuring that the Medicare program is operated in the manner specified by Congress and is protected from fraud and abuse. Therefore, Plaintiff cannot show that it is entitled to injunctive relief, and its preliminary injunction motion should be denied.

V. ARGUMENT

A. This Court Lacks Subject-Matter Jurisdiction to Hear Plaintiff's Claims.

At the outset, the Court should dismiss Plaintiff's action because Plaintiff cannot establish that this court has subject-matter jurisdiction over its challenge to the Secretary's decision to suspend Plaintiff's payments. *See* Def. Mot. To Dismiss (Doc 14); *see also Abet Life, Inc. v. Azar*, 2020 WL 3491966 (No. 4:20-cv-01169) (S.D. Tex. 2020) (Dismissing, *sua sponte*, plaintiff's claims challenging a Medicare payment fraud suspension during COVID-19) (*appeal filed*); *Bridgett Memorial Healthcare v. Azar*, No. 4:20-cv-01770 (S.D. Tex. Oct. 15. 2020) (Dismissing plaintiff's claims challenging a Medicare payment fraud suspension during COVID-19); *True Health Diagnostics, LLC v. Azar*, 392 F.Supp.3d 666 (E.D. Tex. 2019) (court lacked jurisdiction over plaintiff's action challenging a Medicare payment suspension). Put simply, Congress has not waived sovereign immunity to allow Plaintiff to sue the government because it is dissatisfied with the Secretary's suspension decision. While Plaintiff argues that the Court

¹ Where Congress has consented to suit against the government, it may define the terms and conditions under which it is willing to allow the United States to be sued. *See Block v. North Dakota ex rel. Bd. of Univ. & Sch. Lands*, 461 U.S. 273, 274 (1983). And "[w]hen Congress attaches conditions, such as statute of limitations, to legislation waiving the United States' sovereign immunity, those conditions must be strictly observed, and exceptions thereto

has jurisdiction under 28 U.S.C. § 1331, 42 U.S.C. §§ 1395ff, 1395ii and 405(g). However in 42 U.S.C. § 405(h)² – applied to Medicare actions by 42 U.S.C. § 1395ii – Congress excluded 28 U.S.C. § 1331 jurisdiction for Plaintiff's claims since its claims arise under the Medicare Act.³ "The Medicare Act severely restricts the authority of federal courts by requiring 'virtually all legal attacks' under the Act to be brought through the agency" and its administrative exhaustion procedures. *Physician Hospitals of America, v. Sebelius*, 691 F.3d 649, 653 (5th Cir. 2012) (quoting *Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 13 (2000)). The third sentence of 405(h) expressly precludes subject matter jurisdiction under 28 U.S.C. § 1331, and most other jurisdictional grants, when a cause of action "arises under" the Medicare Act. *Ill. Council*, 529 U.S. 1 (2000).

Likewise, Plaintiff cannot establish jurisdiction under 42 U.S.C. §§ 405(g), 1395ff(b) or 1395ii. Subsection 42 U.S.C. § 405(g), on its face, only applies to Social Security decisions made by the Social Security Commissioner and not Medicare decision made by the Secretary. And while 1395ff(b)(1)(A) waives sovereign immunity and allows a party to seek judicial review of a Medicare reimbursement decision under section 405(g), it only does so if a party requires an initial determination[s] under subsection (a)(1), a redetermination decision and a reconsideration decision. 42 U.S.C. § 1395ff(a)(3)(B)(i), (b)(1)(A). Plaintiff has not alleged that the suspension decision was an initial determination, that it received a redetermination or that it received a reconsideration. Indeed, payment suspensions are considered temporary withholdings of

are not to be lightly implied." Id.

² 42 U.S.C. § 1395ii applies 42 U.S.C. § 405(h) that statutory subsection to the entire Medicare Act. *See* 42 U.S.C. § 1395ii (applies "subsections (a), (d), (e), (h), (i), (j), (k), and (l) of section 405" to the Medicare Act.)

³ "A claim arises under the Medicare Act if 'both the standing and the substantive basis for the presentation' of the claim is the Medicare Act, or if the claim is 'inextricably intertwined' with a claim for Medicare benefits."

RenCare, Ltd. v. Humana Health Plan of Tex., Inc., 395 F.3d 555, 557 (5th Cir. 2004) (quoting Heckler v. Ringer, 466 U.S. 602, 606, 623 (1984)) (internal citations omitted). Here, Plaintiff's claims are premised on the Medicare Act, its claimed entitlement to receive Medicare payments and its patients' entitled to Medicare benefits. See Dkt. Doc. 2 at ¶¶ 47, 54, 60. Thus Plaintiff's claims "arise under" the Medicare Act, regardless of precisely how they are couched or presented. See Shalala v. Ill. Council on Long Term Care, Inc., 529 U.S. 1, 10 (2000)

payment, as opposed to a final determination under the Medicare program. *Clarinda Home Health v. Shalala*, 100 F.3d 526, 529 (8th Cir. 1996) ("the withholding is nothing more than a temporary measure necessary to maintain the status quo while the necessary facts are gathered and evaluated"). Finally, 42 U.S.C. § 1395ii, does not waive sovereign immunity or provide federal court jurisdiction.⁴ Therefore, the Court should dismiss Plaintiff's action for lack of subject matter jurisdiction.

B. Plaintiff Does not Meet The Requirements For A Preliminary Injunction Because Plaintiff Cannot Clearly Show A Substantial Likelihood Of Success On The Merits Of Its Due Process Claims.

Even if the Court found that it had jurisdiction over Plaintiff's claims, Plaintiff is not entitled to a mandatory preliminary injunction on its due process claim. Plaintiff asserts that the Secretary has violated its procedural due process rights by suspending its Medicare payments without a pre-suspension hearing. *See* Doc. 9 at 20, 27-29. Plaintiff seeks an injunction ordering the Secretary to remove the payment suspension, pay the suspended payments in escrow and provide a hearing. *See* Doc. 9 at 7. Plaintiff, in seeking a mandatory injunction, must show that the facts and law are clearly in its favor. *See Exhibitors Poster Exch.*, 441 F.2d at 561. Plaintiff fails to meet this burden.

Plaintiff cannot point to any statute, regulation or court decision that prohibits the Secretary from suspending its Medicare payments after receiving credible allegations of fraud.

Instead, the facts and the law clearly favor the Secretary. Medicare statutes and regulations specifically authorized the Secretary to suspend Medicare payments when he received a credible

⁴ Section 1395ii states "[t]he provisions of sections 406 and 416(j) of this title, and of subsections (a), (d), (e), (h), (i), (j), (k), and (l) of section 405 of this title, shall also apply with respect to this subchapter to the same extent as they are applicable with respect to [the Medicare Act], except that, in applying such provisions with respect to this subchapter, any reference therein to the Commissioner of Social Security or the Social Security Administration shall be considered a reference to the Secretary or the Department of Health and Human Services, respectively." However, §1395ii does not apply subsection (b) (which provides administrative law judge hearings) nor subsection (g) (which provides judicial review) to the Medicare Act'.

allegation of fraud. *See* 42 U.S.C. § 1395y(o). The Secretary suspended Plaintiff's Medicare payments after he received credible allegations that Plaintiff repeatedly submitted noncompliant claims for payment and may have misrepresented services billed to the Medicare program. Attach. A at 1. Furthermore, Courts have repeatedly refused to hear or denied challenges to the Secretary's authority to suspend Medicare payments. *True Health Diagnosis v. Azar*, 392 F. Supp. 3d at 684 (E.D. Tex. 2019); *Cplace Springhill SNF, LLC v. Burwell*, 2015 WL 1849499 (W.D. La 2015); *Friedman & Associates v. Pennsylvania Blue Shield*, 836 F. Supp. 263 (E.D. Pa. 1993); *Arecibo Medical Hospice Care v. Shalala*, 1994 WL 448678 (D. Puerto Rico); *In re St. John's Home Health Agency, Inc., v. Bowen*, 173 B.R. 238, 242-46 (Bankr. S.D. Fla. 1994), *Integrated Generics, Inc., v. Bowen*, 678 F. Supp. 1004, 1007 (E.D.N.Y. 1988).

As discussed below, Plaintiff has also failed to satisfy the due process elements established by the Supreme Court in *Mathews v. Eldridge*, 424 U.S. 319, 335 (1976). Courts weigh the three *Eldridge* factors when determining whether the procedural due process provided is adequate. The *Eldridge* elements are: (1) the private interest that will be affected by the official action; (2) the risk of an erroneous deprivation of such interest through the procedure used, and the probable value, if any, of additional or substitute procedural safeguards; and (3) the Government's interest, including the function involved and the fiscal administrative burdens that the additional or substitute procedural requirement would entail. *Mathews v. Eldridge*, 424 U.S. 319, 335 (1976). Plaintiff fails to clearly show that it has a justiciable due process claim under *Eldridge*. Therefore, Plaintiff fails to meet its burden of clearly establishing a substantial likelihood of success on the merits of its claims.

1. Plaintiff cannot satisfy the first *Eldridge* factor because Plaintiff cannot clearly show that it has a property interest in Medicare reimbursements potentially fraudulent Medicare reimbursements after the Secretary receives a credible allegation of fraud.

Plaintiff states it has a substantial interest in the receipt of Medicare payments for covered services it has rendered that ultimately affects its private interest in the survival of its business. Doc. 9 at 23. Plaintiff argues that it has a protected property interest in payments for services that are covered under the Medicare Act and actually rendered. Doc. 9 at 25-27. However, Plaintiff has not established that it has a clear right to potentially fraudulent Medicare payments.

a. The Medicare Act authorized the Secretary to suspend Plaintiff's Medicare payments after receiving credible allegations of fraud.

Congress authorized the Secretary to suspend Medicare payments when it receives credible allegations of fraud. 42 U.S.C. § 1395y(o). Medicare payment suspension is a tool that Congress gave the Secretary to protect the Medicare Trust Fund from problematic providers. Specifically, Congress authorized the Secretary - when he receives such allegations - to temporarily suspend payments to a provider unless the Secretary determines there is good cause not to suspend such payments. 42 U.S.C. § 1395y(o)(1); 42 C.F.R. § 405.371. During this period, the Secretary continues to process claims but does not make payment. *Neurological Associates - H. Hooshmand v. Bowen*, 658 F. Supp. 468, 471 (S.D. Fla. 1987). Courts have upheld payment suspensions based on billing irregularities, *Friedman & Associates v. Pennsylvania Blue Shield*, 836 F. Supp. 263 (E.D. Pa. 1993), or where overpayments are merely "suspected," *Arecibo Medical Hospice Care v. Shalala*, 1994 WL 448678 (D. Puerto Rico). *See also In re St. John's Home Health Agency, Inc., v. Bowen*, 173 B.R. 238, 242-46 (Bankr. S.D. Fla. 1994), *Integrated Generics, Inc., v. Bowen*, 678 F. Supp. 1004, 1007 (E.D.N.Y. 1988).

Here, the Secretary's suspension of Medicare payments action is based on credible

allegations of fraud. Those allegations include Plaintiff's submission of claims that do not meet Medicare requirements. Attach. A at 1. The Secretary determined there was no good cause to not implement the suspension. Therefore, pursuant to the Secretary's regulations at 42 C.F.R. § 405.370 *et seq.*, the Secretary was duly authorized to suspend payments to Plaintiff.⁵

b. Plaintiff cannot clearly show that it has a right receive Medicare payments when the Secretary receives a credible allegation of fraud.

Plaintiff asserts that it has a property interest in its Medicare reimbursements. Doc. 9 at 20-21. However, the 5th Circuit has already determined that such a right does not exist. In *Personal Care Products, Inc. v. Hawkins*, 635 F.3d 155, 158 (5th Cir. 2011), the Court explained that property interests "are not created by the Constitution." *Id.* at 158. Rather, property interests are "created and their dimensions are defined by existing rules or understandings that stem from an independent source such as" state or federal laws. *Id.* The court, which rejected a materially identical due-process claim by a Medicaid provider, ruled that the statutory schemes that allow governmental agencies to withhold funding because of fraud investigations do not create property rights to those payments – even the payments that were not under investigation. *See id.* at 159.

And while Plaintiff claims it has a right to receive Medicare payments, it does not point to any statute, legal rule, or mutually explicit understanding between the parties that gives Plaintiff the right to receive Medicare payments when the Secretary receives a credible allegation that Plaintiff is submitting fraudulent claims. Plaintiff admits that Medicare regulations allow the Secretary to suspend Medicare payments after receiving a credible allegation of fraud.

Compl. ¶¶ 25-28. And Plaintiff also admits that the Secretary suspended payments based on

⁵ As a result, Plaintiff also fails to show a substantial likelihood of success on its *ultra vires* claims. *See* Doc. 1 at ¶¶ 79-82.

credible allegations of fraud concerning its Medicare claims—namely that Plaintiff misrepresented services billed to the Medicare program. *Id.* ¶ 3.

Indeed, in the certification section of the Centers for Medicare & Medicaid Services (CMS) Form 855B, Plaintiff recognized that its right to Medicare payments is controlled by and conditioned on Medicare law regulations and programs instructions when it certified⁶ that:

I agree to abide by the Medicare laws, regulations and program instructions that apply to this provider. The Medicare laws, regulations, and program instructions are available through the Medicare contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the provider's compliance with all applicable conditions of participation in Medicare.

Medicare Enrollment Application – Institutional Providers, CMS-855B (revision date Jul. 1, 2011), at 48, https://www.cms.gov/medicare/cms-forms/cms-forms/downloads/cms855b.pdf. Therefore, Plaintiff accepted that Medicare statutes and regulations controlled when he would receive payments and those statutes and regulations allow the Secretary to suspend Plaintiff's Medicare payments after receiving a credible allegation of fraud. Thus, Plaintiff does not have a property interest in its Medicare reimbursements. See True Health, 392 F. Supp. 3d at 684 (E.D. Tex. 2019) (Finding that plaintiff's allegation the Secretary CMS violated its procedural due process right by suspending its Medicare reimbursements without providing any pre- or post-deprivation process to challenge the actual basis of the suspension is without merit.)

But Plaintiff still tries to claims that it has a property interest in its Medicare payments that supersedes clear Medicare statutes and regulations. To support its assertion, Plaintiff relies on the district court's decision in *Family Rehabilitation, Inc. v. Azar*, 2020 WL 230615 (N.D. Tex. Jan. 15, 2020) to argue that it has a protected property interest in receiving Medicare

⁶ Plaintiff, like all Medicare providers, must complete this certification found in the CMS form 855A when they seek admission into the Medicare program, and anytime providers change information in their Medicare enrollment file.

payments and asserts that the Secretary's fraud suspension during the COVID-19 pandemic denies its property interest. Doc. 9, at 20-21. However, *Family Rehabilitation* does not support Plaintiff's assertions. In *Family Rehabilitation*, the court found that the plaintiff had a legitimate claim of entitlement to payment for services rendered because "there is no allegation that Family Rehab knew these services were not covered or was attempting to commit fraud." *Family Rehab.*, 2020 WL 230615 at *7. Here, Plaintiff's payments were suspended based on fraud allegations, therefore *Family Rehab* does not apply. *See id.* As such, Plaintiff cannot meet the second *Eldridge* factor.

c. Plaintiff cannot clearly demonstrate that the COVID-19 Pandemic establishes good cause to not impose a Medicare payment suspension when the Secretary has received credible allegations of fraud.

Plaintiff argues that the Secretary abused his discretion by not finding good cause to not impose the suspension due to the COVID-19 pandemic. Doc. 9, at 15. However, Plaintiff cannot point to any authority that prohibits the Secretary from imposing a Medicare payment suspension when he receives credible allegations of fraud. The Secretary – through CMS – used his authority and discretion granted under section 1812(f) of the Social Security Act to take proactive steps to respond to the COVID-19 emergency. Specifically, the Secretary issued waivers allowing regulatory flexibilities to help healthcare providers contain the spread of COVID-19. The Secretary issued waivers that relax certain requirements for Medicare providers and suppliers – including ambulance service providers – from March 1, 2020 through the end of the COVID-19 emergency declaration.

⁷ Coronavirus Waiver & Flexibilities, CMS.gov, https://www.cms.gov/about-cms/emergency-preparedness-response-operations/current-emergencies/coronavirus-waivers (last visited May 12, 2020).

⁸ COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers, https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf (last visited May 12, 2020); (Attach. D).

However, Congress has not required the Secretary to issue waivers that eliminate the statutory and regulatory requirements for ambulance service providers or stop ambulance service provider payment suspensions based on credible allegations of fraud. As a result, the Secretary exercised his discretion to suspend Plaintiff's Medicare payments. Plaintiff cannot point to any authority that prohibits the suspension due to the COVID-19 emergency. Therefore, the COVID-19 emergency does not provide Plaintiff with a basis for unfettered access to the Medicare Trust Fund nor does it provide a basis to terminate the Medicare payment suspension when there are credible allegations of fraud.⁹

2. Plaintiff cannot satisfy the second *Eldridge* factor because Plaintiff cannot clearly demonstrate that its request for a hearing will add significant probable value.

Plaintiff asserts - without support - that the Secretary suspending its payments without a hearing to contest the adverse action violates Due Process of Law. Under *Eldridge*, the Court required, as part of its second element, a review of the "probable value, if any, of additional procedural safeguards." *Eldridge*, 424 U.S. at 343-345. Plaintiff, relying on *Eldridge*, argues that due process requires that it be given the opportunity to have a hearing before the Secretary suspended its payments. Doc. 9, at 22. *Eldridge*, however, does not support Plaintiff's assertions.

The Due Process Clause does not guarantee an evidentiary hearing, it only guarantees the baseline amount of process sufficient to ensure that a proceeding is fair. "The type of hearing necessary—the process due—is a function of the context of the individual case." *Jones v. La Bd. of Sup'rs of Univ. of La. Sys.*, 809 F.3d 231, 236 (5th Cir. 2015). In *Eldridge*, the Supreme Court recognized that the due process right to a hearing relies on the nature of the decisionmaking

⁹ Plaintiff also fails to show a substantial likelihood of success on its claim that the suspension is arbitrary and capricious because the Secretary failed to find good cause to not impose the suspension due to the COVID-19 pandemic. *See* Doc. 1 at ¶¶ 72-77.

process. See Eldridge, 424 U.S. at 343-44. The Court stated that "[c]entral to the evaluation of any administrative process is the nature of the relevant inquiry." *Id.* at 343. The Court explained that "procedural due process rules are shaped by the risk of error inherent in the truthfinding process as applied to the generality of cases, not the rare exceptions." *Id.* at 344. While Social Security disability denials are permanent decisions that require a medical assessment of the worker's physical or mental condition, the Court concluded that those decisions "turn, in most cases, upon "routine, standard, and unbiased medical reports by physician specialists concerning a subject whom they have personally examined. *Id.* (internal citation omitted). The Court concluded that hearings were not required because the "specter of questionable credibility and veracity is not present." *Id.*

The risk of error here is even less than the Social Security disability process that the *Eldridge* court examined (and found that a hearing was not necessary). Congress authorized fraud payment suspensions when the Secretary receives a credible allegation of fraud. *See* 42 U.S.C. § 1395y(o). The allegations can come from any source, including, fraud hotline complaints, claims data mining and patterns identified through provider audits, civil false claims cases, and law enforcement investigations. 42 C.F.R. § 405.370(a). To determine if an allegation is credible, the Secretary does not have to resolve factual findings, but only has to determine if the allegation has an "indicia of reliability." *Id.* Medicare statutes and regulations gave the Secretary the discretion to determine if the suspension was necessary to protect the Medicare trust fund. *See* 42 U.S.C. § 1395y(o); 42 C.F.R § 405.371(a)(2). The Secretary's payment suspensions is not final determinations but is a temporary action while the Secretary determines if the allegations are true. *See* 42 C.F.R. §§ 405.371(a)(2); 405.372(e)(3)(ii). If the Secretary decides to continue the suspension, he must evaluate the suspension every 180 days to

determine whether there is good cause not to continue the suspension. *Id.* at § 405.371(b)(2)(i). Fraud suspensions cannot continue after the fraud investigation ends or if the Secretary finds no good cause to continue the suspension. 42 C.F.R §§ 405.371(b), 405.372(d)(3)(ii).

When the Secretary suspends payments, he must give a provider at least 15 days to submit any statement (including any pertinent information) as to why its payments should not be suspended. 42 C.F.R. § 405.374(a). The Secretary provided Plaintiff with the opportunity to respond to the suspension and Plaintiff submitted a rebuttal response. In its rebuttal, Plaintiff argued that its payment should not be suspended because of 1) the COVID-19 emergency and the Plaintiff's viability during said emergency; 2) federal regulations providing that CMS must have good cause to suspend a provider or supplier's Medicare payments where it is determined that beneficiary access to items or services could be jeopardized; 3) a claim of constitutional right to payments for services rendered under the Due Process clause; and 4) the constitutional right of Medicare beneficiaries to access safe and reliable services. Attach. B, at 2. In a detailed response, the Secretary considered but rejected Plaintiff's assertions one by one, stating that the COVID-19 pandemic did not justify termination of the suspension when there are potentially fraudulent claims and that there were other ambulance providers available to provide services to Plaintiff's patients if Plaintiff could not continue to do so. Attach. C. Therefore, Plaintiff had "notice and an opportunity to be heard." See Eldridge, 424 U.S. at 333.

At bottom, fraud suspension decisions turn on the receipt of a credible fraud allegation and whether the Secretary should exercise his discretion to impose the suspension or find good cause not to suspend. The only questions that the Secretary has to resolve before imposing the suspension are whether the allegations have an indicia of reliability and how the suspension would impact the Medicare program. Therefore, fraud suspensions decisions do not require

provider hearings with evidentiary submissions and factual findings. While Plaintiff asserts that it is entitled to a hearing before its payments are suspended, Plaintiff does not cite to any legal authority supporting its assertion nor does it explain what it would present a a hearing that it could not present in its rebuttal statement. Therefore, like the Court found in *Eldridge*, an evidentiary hearing is not likely to add significant probable value to the suspension process.

3. Plaintiff cannot satisfy the third *Eldridge* factor because Plaintiff cannot clearly demonstrate that its interest in having a pre-suspension hearing is greater than the Government's interest in protecting the Medicare Trust fund.

The final factor to be considered in striking an appropriate due process balance is the public interest. *Eldridge*, 424 U.S. at 347 ("[t]his includes the administrative burden and other societal costs that would be associated with requiring, as a matter of constitutional right, an evidentiary hearing upon demand in all cases prior to the termination of benefits."). The Court noted that "an evidentiary hearing is neither a required, nor even the most effective, method of decisionmaking in all circumstances." *Id.* at 348. "All that is necessary is that the procedures be tailored, in light of the decision to be made, to 'the capacities and circumstances of those who are to be heard,' to insure that they are given a meaningful opportunity to present their case." *Id.* at 349 (citation and quotation omitted).

Here, the Government's interest in protecting the Medicare Trust Fund is greater than the Plaintiff's interest in having an ALJ hearing before recoupment can begin. To ensure that Medicare beneficiaries receive the medical services that they need, Congress established a payment system in which suppliers are paid promptly (normally without review of the claims). See 42 U.S.C. § 1395ff(a)(2)(A). However, the Medicare Program is not a bottomless well of money that continuously replenishes itself. The Congressional Research Services estimates that Medicare Part B, which pays for ambulance services that Plaintiff provides, will become

insolvent in 2026. ¹⁰ Therefore, to protect the Medicare Trust fund from fraud, abuse and waste and ensure that Americans can still receive Medicare Part B benefits, Congress allows the Secretary to immediately suspend Medicare providers when he receives a credible allegation of fraud. 42 U.S.C. § 1395y(o). The reasoning is obvious. If the Secretary discovers that a provider is fraudulently billing the Medicare program, the longer that provider is allowed to submit claims, the greater the loss to the Medicare program.

Therefore, the Government's interest in prolonging the solvency of the Medicare program so that that beneficiaries can continue to receive services is far greater than the interest of Plaintiff - a for-profit business that has presumably damaged the solvency of the program by submitting fraudulent claims – to delay a fraud payment suspension under the guise of needing a hearing. Thus, Plaintiff has failed to state a due process violation and its request for injunctive relief should be dismissed.

C. Plaintiff Cannot Clearly Show a Likelihood of Success on Its Patient's Due Process Claims.

Plaintiff asserts that the Secretary is violating its patients' rights by denying its patients' access to Medicare. Doc. 9, at 29. However, Plaintiff filed nothing to indicate that it has standing to represent its patients' due process claims. "Federal courts have subject matter jurisdiction only over a 'case' or 'controversy." *Deutsch v. Annis Enterpr. Inc.*, 882 F.3d. 169, 173 (5th Cir. 2018). "To establish a 'case or controversy,' a plaintiff must show that he has standing to sue." *Id.* (citing *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560–61 (1992)). Therefore, a plaintiff "must establish that (1) he has suffered an injury in fact—an invasion of a legally protected interest which is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical, (2) there is a causal connection between the injury and the conduct

¹⁰ *Medicare: Insolvency Projections – May 29, 2020 Update*, Congressional Research Service, https://fas.org/sgp/crs/misc/RS20946.pdf. (Attach. E).

complained of, and (3) it is likely ... that the injury will be redressed by a favorable decision." *Id.* (internal quotations and citations omitted). Plaintiff has not demonstrated that it has standing to bring a due process claim on behalf of its patients.

Plaintiff cannot establish standing for at least two reasons. First, Plaintiff cannot establish that it represents its patients or that it will suffer a concrete, actual or imminent injury if its patients are denied healthcare. Rather, Plaintiff asserts that its patients *may* suffer an injury if the Secretary suspends Plaintiff's payments because its patients *might* not be able to find another ambulance service provider *if* it goes out of business. *See* Doc. 9, at 29.

Second, Plaintiff cannot establish a causal connection between the injury and the conduct complained of. If Plaintiff chooses to not provide services to Medicare beneficiaries (which it is free to do) then it would be Plaintiff, and not the Secretary that forces Plaintiff's patients to seek another provider. And, contrary to Plaintiff's assertions, there are a sufficient number of ambulance service providers to serve Plaintiff's patients. There are 54 other ambulance service providers in Hidalgo County and the surrounding four counties serving the area served by Acute Care. Attach. C, at 2. Therefore, the Secretary asserts that the Court should deny Plaintiff's request for lack of standing.

Additionally, even if Plaintiff can establish standing, this Court would not have jurisdiction to hear this claim. If Plaintiff's patients are denied Medicare services, which Plaintiff has not stated has occurred, they will have the right to challenge the claim denial through the Secretary's administrative appeals process. Indeed, Plaintiff's patients must channel Medicare service denials through the administrative process before this Court can exercise jurisdiction. See Shalala v. Ill. Council on Long Term Care, Inc., 529 U.S. 1, 13 (2000); Physician Hospitals of America, 691 F.3d at 653. Therefore, the Secretary asserts that the Court

should deny Plaintiff's request for lack of subject matter jurisdiction.

Even if Plaintiff could establish standing and jurisdiction, Plaintiff, in seeking a mandatory injunction, must show that the facts and law are clearly in its favor. *See Exhibitors Poster Exch.*, 441 F.2d at 561. Plaintiff fails to meet this burden. Plaintiff cannot point to any statute, regulation or case that gives ambulance service patients a right to receive services from a Medicare provider under a fraud payment suspension.

Additionally, in *O'Bannon v. Town Court Nursing Center*, 447 U.S. 773 (1980), the Supreme Court held that Medicare beneficiaries do not have a due-process right to a hearing before their provider's authority to render services is terminated. In *O'Bannon*, approximately 180 elderly residents of a nursing home claimed "a constitutional right to a hearing before a state or federal agency may revoke the home's authority to provide them with nursing care at government expense." 447 U.S. at 775. The Supreme Court rejected the constitutional claim, even though it recognized that the revocation may have "severe physical or emotional side effects" on the patients. *Id.* at 784. Therefore, Plaintiff cannot clearly show a likelihood of success on its patients' due process claims.

D. Plaintiff Cannot Clearly Show Irreparable Harm.

Plaintiff has failed to satisfy the second requirement to obtain injunctive relief – Plaintiff cannot show irreparable harm. *Canal Auth. of State of Florida v. Callaway*, 489 F.2d at 572. "Mere injuries, however substantial, in terms of money, time and energy necessarily expended in the absence of [an injunction], are not enough. The possibility that adequate compensatory or other corrective relief will be available at a later date, in the ordinary course of litigation, [weighs] heavily against a claim of irreparable harm." *Morgan v. Fletcher*, 518 F.2d 236, 240 (5th Cir.1975) (quoting *Va. Petroleum Jobbers Ass'n v. Fed. Power Comm'n*, 259 F.2d 921, 925

(D.C.Cir.1958)). The party seeking a preliminary injunction must show that the threatened harm is more than mere speculation. *Janvey v. Alguire*, 647 F.3d 585, 601 (5th Cir. 2011). "Severe economic impracticability" is also not enough for a party to avoid channeling its claims through the relevant agency. *Physician Hosps. of Am. v. Sebelius*, 691 F.3d 649, 655 (5th Cir. 2012).

Plaintiff's contention that it will be forced out of business if the suspension continues is entirely unsubstantiated. Even if the contention was true, it will not support injunctive relief because such economic threat does not constitute irreparable harm. "[E]ven if the Secretary's actions were to force a health care provider out of business, the injuries are not necessarily 'irreparable,' considering the risk known to the health care provider when it enters the Medicare program." *Griego v. Leavitt*, 2008 WL 2200052, at *11 (N.D. Tex. May 16, 2008) (quoting *Manakee Prof'l Med. Transfer Serv.*, 71 F.3d 574, 581 (6th Cir. 1995)) (Also finding that plaintiff would not suffer irreparable injury by being forced to exhaust his administrative remedies). ¹¹ Plaintiff voluntarily entered into the Medicare program, and it voluntarily structured its business so that approximately 90% of its revenue is Medicare dependent. Doc. 9, at 10. This Court should not "compel taxpayers to bail out a company because it failed to properly manage its finances." *See True Health*, 392 F. Supp. 3d at 688. Moreover, the threat of bankruptcy does not satisfy the required showing of irreparable injury. *VNA of Greater Tift Cnty. v. Heckler*, 711 F.2d 1020 (11th Cir. 1983).

In addition, the courts have recognized that a provider's financial need to be subsidized for the care of its Medicare patients is incidental to both the purpose and the design of the

¹¹ See generally, Sampson v. Murray, 415 U.S. 61 (1974) (loss of income is not an irreparable injury); *Physician Hospitals of America v. Sebelius*, 691 F.3d 649, 655 (5th Cir. 2012) ("severe economic impracticability" was not enough for a plaintiff to allege that it cannot channel its claims through the agency); *KMW Int'l, v. Chase Manhattan Bank, N.A.*, 606 F.2d 10, 15 (2d Cir. 1979) (because damages were only financial, preliminary injunction should not have issued.); *Cf. Minnesota Ass'n of Health Care Facilities, Inc. v. Minnesota Dep't of Public Welfare*, 602 F.2d 150, 153-154 (8th Cir. 1979) (participation in Medicaid by a nursing home provider of services is voluntary, and the provider's need is "incidental" to the government program); *Thorbus v. Bowen*, 848 F.2d 901, 904 (8th Cir. 1988) (loss of 60% of gross income due to loss of Medicare and Medicaid not irreparable).

Medicare program. Livingston Care Center v. U.S., 934 F.2d 719, 721; Minnesota Association of Health Care Facilities, Inc. v. Minnesota Department of Public Welfare, 602 F.2d 150, 153-54 (8th Cir. 1979). Any allegation that a provider would be forced to close its doors, and that its employees would suffer economic harm is not a showing of irreparable injury. Landmark Medical Center v. Bowen, 700 F. Supp. 350, 351 (W.D. Tex. 1988); Case v. Weinberger, 523 F.2d 602, 607 (2nd Cir. 1975).

Plaintiff argues that the Secretary's suspension during the COVID-19 pandemic will cause the Plaintiff to go out of business. *See* Doc. 9, at 31. However, the government has provided relief to those impacted by COVID-19 through the CARES Act. ¹² In fact, Plaintiff has accepted \$\$60,363.50 in funding through the CARES Act. Attach. C, at 2. Even assuming that Plaintiff has standing to raise any possible harm to its patients, it is unreasonable to conclude that patients would be deprived services if Plaintiff were to go out of business. *See Affiliated Prof'l Home Health Care Agency v. Shalala*, 164 F.3d 282, 286 (5th Cir. 1999) (Stating that "...it seems unreasonable to conclude that the plaintiff's patients will be deprived of adequate homebased health care if plaintiff is forced out of business."). Even if Plaintiff can establish imminent bankruptcy, the Secretary has reviewed access to care for Plaintiff's Medicare beneficiaries. *See* Attach. C, at 2. CMS found that there are 54 ambulance service providers in Hidalgo County and the surrounding four counties serving the area served by Acute Care. *Id.* Plaintiff cannot show that Medicare beneficiaries would lose Medicare services, if Plaintiff were to go out of business.

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¹² President Trump provided support to healthcare providers fighting the COVID-19 pandemic through the CARES Act and the Paycheck Protection Program and Health Care Enhancement Act that provide \$175 billion in relief funds to hospitals and other healthcare providers on the front lines of the coronavirus response. This funding supports healthcare-related expenses or lost revenue attributable to COVID-19. \$50 billion of the Provider Relief Fund is allocated for general distribution to Medicare facilities and providers impacted by COVID-19, based on eligible providers' net patient revenue. The initial \$30 billion was distributed between April 10 and April 17, and the remaining \$20 billion is being distributed beginning Friday, April 24. CARES Act Provider Relief Fund, HHS.gov, https://www.hhs.gov/coronavirus/cares-act-provider-relief-fund/index.html (last visited May 26, 2020).

There is adequate relief available to Plaintiff, which weighs heavily against the issuance of injunctive relief. *See Morgan v. Fletcher*, 518 F.2d at 240. If the Secretary's fraud investigation does not result in an overpayment determination, the payments held in escrow will be returned to Plaintiff. *See* 42 C.F.R. § 405.372(e). If the Secretary determines that Plaintiff improperly received Medicare payments, the Secretary will issue an overpayment determination which Plaintiff can challenge in the Secretary's administrative process. *See* 42 U.S.C § 1395ff. After Plaintiff administratively exhausts its remedies, the reviewing court, if jurisdiction is otherwise proper, has full power to vindicate any rights grounded in the Constitution, statute or regulation. *See Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 13 (2000). Thus, any "harm" suffered by Plaintiff would be remedied by judicial review, and therefore, would not rise to the level of "irreparable harm." *Sampson*, 415 U.S. at 88. In addition, since a final agency determination has not yet been issued, the threat of irreparable harm remains entirely speculative. *See Janvey v. Alguire*, 647 F.3d at 601. Therefore, Plaintiff has failed to show irreparable harm if injunctive relief is not granted.

E. Plaintiff Cannot Clearly Show That The Balance Of Hardships Tips Sharply In Its Favor.

In contrast to Plaintiff's economic interests and low risk of patient disruption, the Secretary's interest in preserving the integrity of the Medicare program is paramount. Enjoining the Secretary from his lawful responsibilities related to administering the Medicare program serves only to disrupt the congressionally-mandated process for review of Medicare disputes. *Physicians Hosps. of America v. Sebelius*, 691 F.3d 649, 657 (5th Cir. 2012) (a provider's claim that the administrative review process would cause it to incur extraordinary expenses did not except it from the administrative channeling requirement.); *VNA of Greater Tift Cnty.*, 711 F.2d at 1033-35 (noting that the district court holding a full hearing on the merits "seriously disrupts

the congressionally-mandated process."). The Secretary has a strong interest in protecting the Medicare program from financial loss and fraud. This interest would be undermined severely if the Secretary was forced to cease withholding funds before completing his investigation. *See Midwest v. Shalala*, 998 F. Supp. 763 (E.D. Mich. 1998).

In this case, Plaintiff has credible allegations of fraud against it, which include Plaintiff's history of submitting claims that do not meet Medicare requirements. Therefore, the Secretary's interest in protecting the Medicare Trust Fund is outweighed by Plaintiff's economic interest.

F. The Public Interest Does Not Favor Injunctive Relief.

Issuance of the injunction sought by Plaintiff would strongly disserve the public interest. The public interest is served by requiring compliance with Congressional statutes. *True Health*, 392 F. Supp. 3d at 688 (citing Sparrow Barns & Events v. Ruth Farm, Inc., 2019 WL 1560442, at *10 (E.D. Tex. Apr. 10, 2019)). The Secretary has an interest in ensuring that the Medicare program is operated in the manner specified by Congress and is protected from fraud and abuse. The public interest cannot be served when providers such as Plaintiff - that possibly submitted fraudulent claims to Medicare - are allowed unfettered access to the Medicare Trust Fund while the Secretary investigates the credible allegations of fraud. Likewise, public interest is not served when these entities are allowed to circumvent the administrative review process – as well as the wishes of Congress – by compelling Medicare payments without fully exhausting their administrative remedies. Exhaustion is generally required as a matter of preventing interference with agency processes so that the agency may function efficiently and have an opportunity to correct its own errors, to afford the parties and the courts the benefit of its experience and expertise, and to compile a record that is adequate for judicial review. Weinberger v. Salfi, 422 U.S. 749, 765 (1975); Good Samaritan Medical Center v. Secretary of HHS, 776 F.2d 594, 599

(6th Cir. 1985). Therefore, the public interest does not favor injunctive relief.

VI. <u>CONCLUSION</u>

Plaintiff has failed to meet its burden of clearly establishing all four requirements for injunctive relief. Therefore, the Secretary respectfully requests that this Court deny Plaintiff's preliminary injunction motion.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the *Defendant's Response to Plaintiff's*Motion for a Preliminary Injunction was sent via first class mail or electronic mail on October 23, 2020, to:

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